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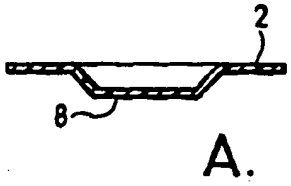
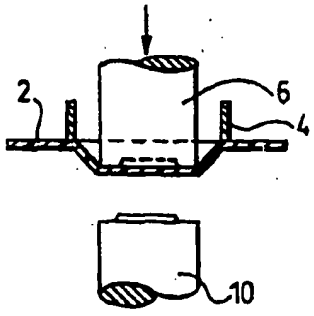
(54) Title: THE FORMATION OF INDICIA IN THE BASE OF A BLISTER PACK FOR TRANSFERENCE TO A BODY CAST THEREIN



A.



B.

(57) Abstract

A laminated film (2) in which a metal foil is sandwiched between two polymeric films is cold formed to define one or more blisters (8), and the base of the blister (8) stamped with indicia (12), in two discrete stages. The blister (8) is formed in the first stage using a standard technique of advancing a pin (6) in a direction transverse relative to the plane of the film (2). According to the invention, once the blister (8) forming stage is completed, indicia (12) are stamped into the base of the blister (8) in the second stage by advancing a die (10, 14) from one side thereof to clamp the blister (8) base against a mould held against the other side. The direction of the die (10) and disposition of the die (10) and mould may be selected such that the indicia (12) project inwardly or outwardly from the blister (8) base.

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THE FORMATION OF INDICIA IN THE BASE OF A BLISTER PACK FOR TRANSFERENCE TO A BODY CAST THEREIN

This invention relates to the use of a laminated film to form blister packs in the blisters of which bodies are cast. Such blister packs typically comprise polymeric films in which the blisters are heat formed. The present invention is particularly concerned with the use of laminated films in which a metal foil is sandwiched between two polymeric layers.

Blister films are particularly suited for the casting of frangible bodies which comprise some pharmaceuticals. These bodies are commonly made using lyophilisation or freeze-drying processes, but alternative techniques such as those including a solid state dissolution stage are also used. The liquid material of the body is poured into the blister or blisters, and then subjected to various treatments while still in the blisters. The products remain in the blister until they are ready for use and at this stage they are readily extractable.

Polymeric blister films suffer from the disadvantage of being permeable, with the consequence that however well the individual blisters are sealed, there is always a potential storage problem if the contents of the blister must be protected from the surrounding atmosphere. With the above points in mind, laminated blister films have been developed in which a metal foil is sandwiched between

polymeric films on either side. Such films are less permeable than all-polymeric films, but some known films can become distorted when subjected to heat treatments, generating irregularity in the cast products and making subsequent handling of the blister pack more difficult. Although some laminated films have been developed which are more stable under heat treatment; see our published European Patent Specification Nos. 0 646 367 and 0 710 101, generally these laminated films are not suitable for the hot-forming of blisters therein. The metal foil core, normally of aluminium, is much better suited to cold forming.

There is currently a strong demand for products cast in blister films as described above to bear some indelible marking. To meet this demand, a hot formed blister can readily be adapted to bear indicia on its internal surface, which indicia are then reflected in the respective surface of the cast product. However, with laminated foils of the kind to which this invention relates, it is difficult if not impossible to create indicia on the inner face of the blister base simultaneously with the formation of the blister itself.

In the present invention, a laminated film comprising a metal foil and a polymeric film on either side thereof is cold formed to define one or more blisters, and the base blister stamped with indicia, in two discrete stages. The blister is formed in the first stage using a standard

technique of advancing a pin in a direction transverse relative to the plane of the film. However, according to the invention, once the blister forming stage is completed, indicia are stamped into the base of the blister in the second stage by advancing a die from one side thereof to clamp the blister base against a mould held against the other side. The direction of the die and disposition of the die and mould may be selected such that the indicia project inwardly or outwardly from the blister base.

Normally, in the practice of the invention the pin used in the formation of the blister itself will be a standard item with a plane flat end face across which the base of the blister is stretched. However, there can be circumstances in which the end face of the pin can be other than flat; for example, it can have the form of a shallow cone to assist in determining the manner in which the blister base is stretched. The end face of the pin can also have formed therein the mould against which a die is advanced to emboss the indicia into the blister base. However, it is normally preferred that during the initial blister formation step there is a continuous surfacing contact with the blister film across the end face of the pin and accordingly, if the mould is there, it will be filled or covered by a suitable blank.

Alternatively of course, a quite different pin can be used and particularly in this variant, the blister formation step and the indicia formation step are conducted at different stations, although normally in the same machinery.

As noted above, the indicia formation step is quite separate from the blister formation step completed first, although both are cold forming steps. In some respects, the indicia formation step enables the laminates of the blister film itself to relax, and as a consequence the overall strength of the film and the blister itself can be enhanced.

A variety of arrangements and orientations of the die and mould in the indicia formation step can be adopted. For example, a die can be mounted in the pin used in the blister formation step, and advanced therefrom against the mould after the blister formation step is completed. In another arrangement, the mould can be formed in what is effectively a fixed body against which the blister if formed, with the die being moved to clamp the blister base against and into the mould thereafter.

Again as noted above, the present invention is particularly suitable for use in the manufacture of pharmaceutical products of a delicate construction. By providing a means by which a permanent marking can be applied to such products, it is felt that a significant advance has been made.

The invention will now be described by way of example and with reference to the accompanying schematic drawings, wherein:

Figures 1A to 1D show the steps in cold forming a blister in a blister film;

Figures 2A to 2D show the steps in the formation of indicia on the base of a blister so formed; and

Figures 3A to 3C illustrate an alternative procedure to that described with reference to Figures 1 and 2.

Referring first to Figure 1, a base film 2 is delivered to a blister forming station illustrated in Figures 2b to 2d. At the blister forming station, the film is clamped (4) around the periphery of the blister 8 to be formed, and a pin 6 advanced towards the film to make an impression therein as shown in Figure 2c. Once the formation step is completed, the pin 6 and clamps 4 are withdrawn, and the blister film 2 is either moved away entirely, or retained for further treatment.

The indicia formation stage is illustrated in Figures 2a to 2d. Figure 2a shows in cross-section a blister film 2 formed with a blister 8. In Figure 2b a pin 6 is shown advanced downwardly into the blister 8 and has a mould in the end face thereof against which the indicia 12 are formed. The pin 6 is held in place by a locking mechanism (not shown) while the die 10 is brought upwardly as shown to clamp the blister base thereagainst and emboss the indicia 12 thereinto. This stage is shown in Figure 2c. Finally, the die 10 and mould are withdraw releasing the blistered and embossed film 2 for transfer to the casting station.

An alternative procedure is shown in Figures 3A, 3B and 3C. In this embodiment, the pin 6 has an auxiliary punch 14 slideably mounted therein. In the blister forming stage, the film is clamped (4), and the pin 6 advanced to form the blister as in Figures 1. However, at the end of the pin 6 that engages the film, the face is open and the

film stretched over the open face. The pin 6 is advanced until the stretched film is clamped against a platen 16 in which the indicia 12 are formed. In the indicia formation stage the punch 14 with a complementary dye 18 in its end face is advanced in the pin 6 to mould the indicia in the film at the base of the blister. In this stage, the periphery of the blister base remains clamped between the pin 6 and the platen 16.

In the procedure shown in Figures 1 and 2 the formed indicia project into the blister from its base, and in the procedure shown in Figures 3 the formed indicia project outwardly. However, it will be appreciated that the indicia may be formed in either orientation in both procedures. It will also be noted that in the Figures 3 procedure the film will be stretched over a projecting dye on the platen 16 in the blister formation stage before the punch 14 finally moulds the indicia if the indicia are to project into the finally formed blister.

It should be understood that the invention applies to the application of indicia to be reflected in the respective surface of the cast product in the broadest sense of the term. Thus, any form of marking is included, and particularly marking having a purely functional purpose such as the creation of break lines. Break lines are commonly used on tablets for oral administration where there is an occasional need for only a portion of a tablet to be taken at a particular time. The invention thus has particular value in the formation in a face of a product cast in a

blister pack of indicia or marking which takes the form of or includes a break line. In this respect it will be appreciated that a break line can be effectively formed by a sequence of depressions or grooves; it does not have to be a continuous groove in all circumstances. What is important is that a line of weakness is formed which enables the cast product to be easily broken into two or more pieces as defined by the break line or lines.

CLAIMS

1. A method of forming a laminated film comprising a metal foil and a polymeric layer on either side of the foil with at least one blister the base of which bears projecting indicia for moulding into a body cast therein, which method comprises cold-forming the blister by advancing a pin in a direction transversely relative to the plane of the film; and stamping the indicia into the base of the blister so formed by advancing a die in the opposite direction against a mould held against the inner face of the blister base.

2. A method according to Claim 1 wherein the end of the pin matches the final outline shape of the blister.

3. A method according to Claim 1 or Claim 2 wherein the mould is formed in the end face of the pin used to cold form the blister.

4. A method according to Claim 3 wherein during the formation of the blister the mould cavity is filled with an insert.

5. A method according to Claim 1 or Claim 2 wherein the mould is formed in the end face of a pin different from the pin used in the blister formation step.

6. A method of forming a laminated film comprising a

metal foil and a polymeric layer on either side of the foil with at least one blister the base of which bears projecting indicia for moulding into a body cast therein, which method comprises cold-forming the blister by advancing a pin in a direction transversely relative to the plane of the film; and stamping the indicia into the base of the blister so formed by advancing a die in the same direction against a mould held against the outer face of the blister base.

7. A method according to Claim 6 wherein the die is mounted in the pin used in the blister formation step, and is advanced therefrom after the blister has been formed.

8. A method according to any preceding claim wherein the blister is formed by advancing the pin to clamp the blister base against a fixed body, and wherein the die is advanced from one of the pin and body to force the blister base into the mould formed in the other of the pin and body.

9. A method according to any preceding claim wherein the pin is formed with at least the periphery of its end face being lubricated or self-lubricating to facilitate the cold-forming of the film therearound.

10. A method according to Claim 9 wherein the pin comprises polytetrafluoroethylene.

11. A process for manufacturing a cast product comprising

forming a blistered laminated film using a method according to any preceding claim; and casting the product in said at least one blister such that the indicia stamped into the blister base are reproduced on the corresponding face of the cast product.

12. A process according to Claim 11 wherein the cast product is a pharmaceutical.

13. A process according to Claim 12 or Claim 13 wherein the cast product is subjected to heat treatment in the mould.

14. A process according to Claim 13 wherein the heat treatment comprises lyophilisation.

15. A process according to Claim 12 or Claim 13 wherein the cast product is subjected to solid state dissolution in the mould.

16. A laminated film comprising a metal foil and a polymeric layer on either side of the foil with at least one blister the base of which bears projecting indicia for moulding into a body cast therein, the blister and the indicia on the base thereof being made by cold-forming techniques.

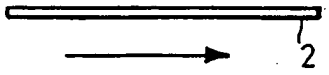


Fig.1A.

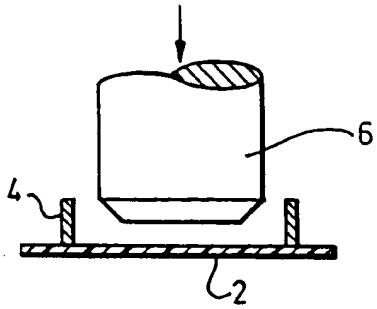


Fig.1B.

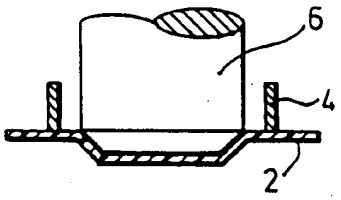


Fig.1C.

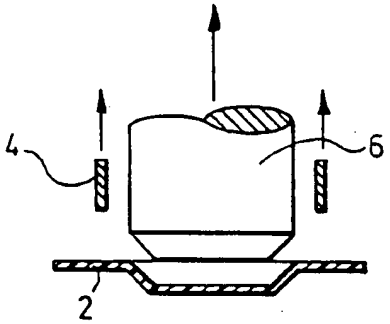


Fig.1D.

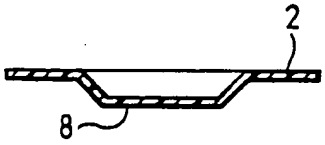


Fig.2A.

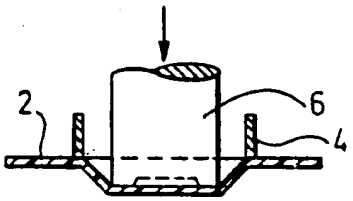


Fig.2B.

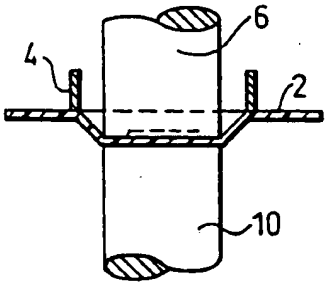
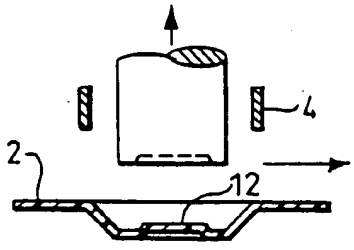


Fig.2C.



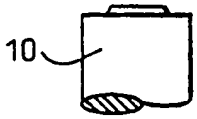


Fig.2D.

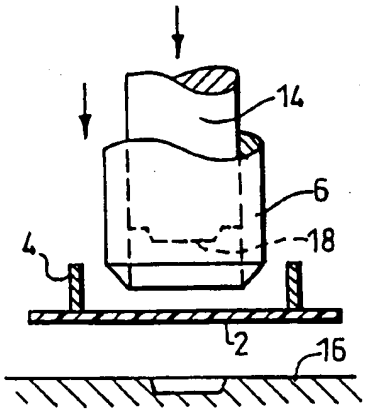


Fig.3A.

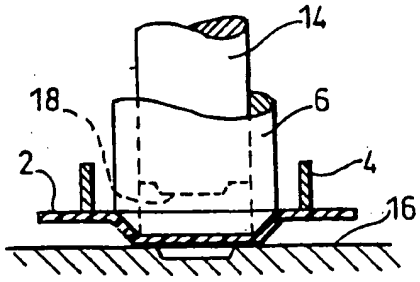


Fig.3B.

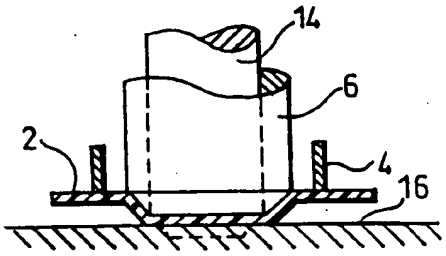


Fig.3C.

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B29C51/08 A61J1/03 B65D75/34 B29C67/00 B29C51/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B29C A61J B65D A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 457 895 A (THOMPSON ANDREW R ET AL) 17 October 1995 see column 4, line 25-74; claims 5-8; figures 3,4 ---	1,6,16
A	WO 97 10162 A (PHARMACIA & UPJOHN AB ;GUSTAFSSON STIG (SE)) 20 March 1997 see abstract; figures ---	1,6,16
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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 646 367 A (SCHERER LTD R P) 5 April 1995 cited in the application see column 2, line 49 - column 3, line 1; figures 1,2	1

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Information on patent family members

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